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UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

KENNETH DUNHAM and  
MARTHA DUNHAM,

Plaintiffs,

v.

COVIDIEN, LP.,

Defendant.

Civil Action No. 1:19-cv-02851-LLS

**STIPULATED PROTECTIVE ORDER**

Plaintiffs Kenneth and Martha Dunham and Defendant Covidien LP (hereinafter the  
“Parties”) hereby agree and stipulate:

**SCOPE OF ORDER**

1. **Application.** This Protective Order applies to all documents, the information contained therein, and all other information produced or disclosed in connection with the above-captioned matter, including all copies, excerpts, summaries, or compilations thereof, whether revealed in a document, deposition, other testimony, discovery response, or otherwise, by the party producing or disclosing the information (“Supplying Party”) to any other party (“Receiving Party”). This Order is binding upon the parties, including their respective corporate parents, subsidiaries, and affiliates, and including their respective attorneys, agents, experts, consultants, representatives, officers, employees, and others as set forth in this Order. This Order is also binding on any person who obtains any documents or other Confidential Information or Highly Confidential Information (as those terms are defined herein) produced or disclosed in connection with the above-captioned matter pursuant to this Order.

2. **Order Shall Not Preclude Other Protective Orders.** The entry of this Order does not prevent any party from seeking a further order pursuant to Federal Rule of Civil Procedure 26(c) or any applicable state procedural rule or provision governing the terms on which disclosure or discovery may be had.

3. **No Effect on Admissibility.** Nothing herein shall be construed to affect in any manner the admissibility at trial or any other court proceeding of any document, testimony, or other evidence.

**DESIGNATION OF CONFIDENTIAL AND HIGHLY CONFIDENTIAL MATERIAL**

4. **Definition of Confidential Material.** “Confidential Information” as used in this Order means any information or tangible thing that the Supplying Party believes in good faith constitutes, reflects, discloses, or contains information subject to protection under Federal Rule of Civil Procedure 26(c) or other applicable laws or regulations. “CONFIDENTIAL” Documents or Information include (1) Documents or Information that contain trade secret information as defined by Section 1(4) of the Uniform Trade Secrets Act, or other confidential research, development, proprietary or commercial information, (2) Documents or Information that are deemed confidential under the U.S. Food & Drug Administration (“FDA”) regulations, Health Insurance Portability and Accountability Act (“HIPAA”) statutes, and (3) Documents or Information containing protected data that a party believes in good faith is subject to federal, state, or foreign data protection laws or other privacy obligations. In designating information as “CONFIDENTIAL,” the Supplying Party will make such designation only as to that information that the Supplying Party reasonably and in good faith believes is entitled to protection.

5. **Definition of Highly Confidential Information.** “Highly Confidential Information” as used in this Order means Confidential Information that if disclosed could result



in substantial business harm to the competitive position of the Designating Party or Producing Party because it contains: (1) research and development material on a new product that has not been approved or cleared by the FDA or similar regulatory body, or (2) reflects a Party's price competitiveness in the market, or (3) is nonpublic marketing or business strategies of a Party concerning a current or new product. Moreover, certain medical records and testimony related to the HIV status of individuals, history of sexually transmitted disease, incidents of sexual or physical abuse, and details related to instances of institutionalization or hospitalization related to emotional and psychological conditions of an individual Plaintiff may also be designated as HIGHLY CONFIDENTIAL. In designating discovery materials as "Highly Confidential," the Supplying Party will make such designation only as to that information that the Supplying Party in good faith believes to be entitled to highly confidential treatment. Where this Order uses the term Confidential Information, it shall apply equally to Highly Confidential Information unless otherwise specified.

6. **Definition of Competitor.** "Competitor" as used in this Order means any company or individual, other than the Supplying Party, that is or plans to be engaged in the design, research, development, testing, manufacture, regulatory review process, sale, marketing, creation, prosecution, pursuit, or other development of an interest in protecting intellectual property, and/or licensing of any product or services involved in any mesh device intended to be implanted in the human body.

7. **Designation of Confidential Information Generally.** Specific documents, items, materials, or communications produced by a Supplying Party shall, if appropriate, be designated as "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" by marking the pages of the document that contain Confidential Information as follows: "CONFIDENTIAL" or "CONFIDENTIAL -

SUBJECT TO PROTECTIVE ORDER” or “HIGHLY CONFIDENTIAL” or “HIGHLY CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER.” Except as provided in Paragraph 10, documents that do not bear the foregoing designations are not Confidential Information as that term is used in this Order.

8. **Designation of Electronic Media by Cover Letter.** To the extent that matter is stored or recorded in the form of electronic or magnetic media (including information, files, databases, or programs stored on any digital or analog machine-readable devices, computers, Internet sites, discs, networks, or tapes (“Computerized Material”)) is produced by any party in such form, the Supplying Party may designate such matters as Confidential or Highly Confidential by cover letter referring generally to such matter. Whenever any party to whom Computerized Material designated as Confidential or Highly Confidential is produced reduces such material to hard copy form, that party shall mark the hardcopy form with the “CONFIDENTIAL” or “CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER” designation or the “HIGHLY CONFIDENTIAL” or “HIGHLY CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER” designation.

9. **Redaction or Withholding.** In order to protect against unauthorized disclosure of Confidential Information or Highly Confidential Information, and to comply with all applicable foreign, state, and federal laws and regulations governing data privacy, the Supplying Party may withhold non-responsive attachments to responsive parent documents and may redact from produced documents, materials, or other things, or portions thereof:

a. **Protected Health Information.** Any information that identifies the individual patient or for which there is a reasonable basis to believe the information could be used to identify the individual will be redacted. Specific identifiers to be redacted include:

names, initials, all geographic subdivisions smaller than a state, including street address, city, county, and zip code information, all elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, and date of death, patient age where the patient is over age 89, telephone numbers, fax numbers, email addresses, social security numbers, medical record numbers, health plan beneficiary numbers, account numbers, certificate/license numbers, vehicle identifiers and serial numbers, including license plate numbers, device identifiers and serial numbers, Web Universal Locators, Internet Protocol address numbers, biometric identifiers, including finger and voice prints, full face photographic images and any comparable images, and any other unique identifying number, characteristic, or code;

b. **Identification of Adverse Event Reporters.** Any similar information which identifies or for which there is a reasonable basis to believe the information could be used to identify adverse event reporters must also be redacted;

c. **Personally Identifiable Information.** Personally identifiable information will be redacted, including social security numbers, individual compensation information, cancelled checks, credit card numbers, tax identification numbers, and bank account numbers;

d. **Trade Secrets.** Trade secrets that would cause an unfair disadvantage to the Supplying Party; and

e. **Other Products.** Any information relating to products other than Parietex Optimized Composite Mesh.

10. **Adverse Event Information Confidential Even If Not Designated.** Pursuant to 21 C.F.R. §§ 314.430(e) & (f) and 20.63(f), the names of any person or persons reporting adverse experiences of patients and the names of any patients that are not redacted pursuant to



Paragraph 9 shall be treated as confidential, regardless of whether the document containing such names is designated as Confidential Information. No such persons shall be contacted, either directly or indirectly, based on the information so disclosed without the express written permission of the Supplying Party.

11. **Challenges to Designations or Redacted Information.** Any party may, at any time, challenge the redaction or the designation of information as Confidential or Highly Confidential by providing written notice to the Supplying Party of each redaction or designation it is challenging and describing the basis for each challenge. The parties shall attempt to resolve each challenge in good faith and must begin the process by conferring directly in person or by phone. If, after a meet and confer process, the parties cannot reach an agreement, the challenging party may, on reasonable notice, apply for an appropriate ruling from the Court. The disputed material shall continue to be treated as designated, or redacted, until the Court orders otherwise. In any such application concerning a ruling on confidentiality or redacted information, the party claiming the designation of confidentiality or redaction has the burden of establishing that such confidential designation or redaction is proper.

12. **Designation of Information Produced by Other Parties.** A party may designate as Confidential Information or Highly Confidential Information any document or information produced by or testimony given by any other person or entity that the party reasonably believes qualifies as such party's Confidential Information or Highly Confidential Information pursuant to this Order. If any third party produces information that any party in good faith believes constitutes its Confidential Information or Highly Confidential Information, the party claiming confidentiality shall designate the information as such within thirty (30) days of its receipt of such information. Any party receiving information from a third party shall treat such information

as Highly Confidential during this thirty (30) day period while all parties have an opportunity to review the information and determine whether it should be designated as confidential. Any party designating third party information as confidential shall have the same rights as a Supplying Party under this Order with respect to such information.

13. **Confidentiality of Deposition Testimony and Use of Confidential Material at Depositions.** All transcripts and exhibits shall be treated as if designated Confidential for a period of forty-five (45) days after the transcript is available from the court reporter, unless the deponent and all Parties waive confidentiality prior to the expiration of such forty-five-day period. Counsel for any party may designate during the deposition or during the forty-five-day period after the transcript is available from the court reporter any portion of the transcript as Confidential or Highly Confidential by denominating by page and line, and by designating any exhibits, that are to be considered Confidential or Highly Confidential pursuant to the criteria set forth in this Order. Such designation shall be communicated to all parties. Transcript portions and exhibits designated in accordance with this paragraph shall be disclosed only in accordance with this Order. A party may challenge the Confidential or Highly Confidential designation or portions thereof in accordance with Paragraph 11 of this Order.

14. **Access to and Storage of Confidential Material.** Materials or items designated as Confidential Information or Highly Confidential Information must be stored and maintained by a Receiving Party at a location and in a secure manner that ensures that access is limited to the persons authorized under this Order. Counsel shall take all reasonable and necessary steps to ensure the security of any Confidential Information or Highly Confidential Information and will limit access to Confidential Information or Highly Confidential Information to those persons authorized by this Order. In particular, if counsel for any party makes documents produced

pursuant to this Order available via the Internet, such counsel shall take all reasonable and necessary steps to ensure that the Internet site is secure and may not be accessed by individuals who are not authorized to review Confidential Information or Highly Confidential Information and who have not executed the Acknowledgement attached as Exhibit A. At a minimum, any Internet site must require each individual user to have a distinct log-in and password. Upon request by a Supplying Party, any party using an Internet site must certify to the Court and the Supplying Party that the Internet site is secure and may only be accessed pursuant to this Order.

15. **Inadvertent Failure to Designate or Redact.** Inadvertent production of any document or information without a designation of Confidential or Highly Confidential will not be deemed to waive a party's claim to its confidential nature or preclude said party from designating said document or information as Confidential or Highly Confidential or redacting it at a later date. Disclosure of said document or information by another party prior to such later designation shall not be deemed a violation of the provisions of this Order.

16. **No Waiver of Privilege or Work Product.** If a Supplying Party discloses information subject to a claim of attorney work product protection or attorney-client privilege or some other legal privilege or doctrine protecting information from disclosure, the disclosure of the information shall not constitute a waiver or forfeiture of any claim of the privilege or work product protection. This provision is, and shall be construed, as an Order under Federal Rule of Evidence 502(d). Accordingly, as explicitly set forth in Rule 502(d), a party's production of protected information, whether inadvertent or intentional, is not a waiver of any privilege or protection "in any other federal or f proceeding."

17. **Return of Confidential Information and Highly Confidential Information Upon Conclusion of Litigation.** Within thirty (30) days after the final termination of this action,



counsel for the Receiving Party, and any persons to whom he or she disclosed Confidential Information or Highly Confidential Information pursuant to this Order, shall return to the Supplying Party and/or destroy any Confidential Information and/or Highly Confidential Information or copies thereof. At the written request of the Supplying Party, any person or entity having custody or control of recordings, notes, memoranda, summaries, or other written materials, and all copies thereof, relating to or containing materials and/or items produced by the Supplying Party and any copies thereof, relating to or containing discovery materials produced by the Supplying Party shall deliver to the Supplying Party within thirty (30) days of the request an affidavit certifying that all such materials and/or items produced by the Supplying Party and any copies thereof, any and all recordings, notes, memoranda, summaries, or other written material regarding the materials and/or items produced by the Supplying Party (except for privileged communications, work product, and court-filed documents) have been delivered to the Supplying Party or destroyed in accordance with the terms of this Order.

#### **DISCLOSURE OF CONFIDENTIAL AND HIGHLY CONFIDENTIAL INFORMATION**

18. **Use of Confidential and Highly Confidential Information Limited to this Action.** Any document or other material which is marked Confidential or Highly Confidential, or the contents thereof, may be used by a party, or a party's attorney, expert witness, consultant, or any other person to whom disclosure is made, only for the purposes of discovery, hearings, trial, appeal, and/or settlement of the above captioned action, and shall not be used in any other proceeding or action.

19. **To Whom Confidential Information May be Disclosed.** A Receiving Party may show and deliver Confidential Information only to the following persons:

- a. Counsel for the Receiving Party, including any in-house counsel, co-

counsel, and the attorneys, paralegals, stenographic, and clerical staff employed by such counsel to whom it is reasonably necessary to disclose the Confidential Information for purposes of this litigation;

b. With respect to any Confidential Information produced by the Plaintiffs or any third party with respect to the Plaintiffs, any employee or agent of the Receiving Party to whom it is reasonably necessary to disclose such Confidential Information for purposes of the litigation;

c. Any outside consultant or expert to whom it is reasonably necessary to disclose Confidential Information and who has signed the "Acknowledgement and Agreement to be Bound" (attached hereto as Exhibit A);

d. Any deponent or witness at deposition, trial, or hearing, for whom it appears on the face of the document that the deponent or witness authored or received a copy of the document containing the information, or is or was employed by the Supplying Party;

e. Any special master, mediator, or arbitrator engaged by the parties or authorized by the Court for purposes of mediation, arbitration, or other dispute resolution regarding issues arising in this litigation;

f. Stenographic employees and court reporters recording or transcribing testimony; and

g. The Court and any members of its staff to whom it is necessary to disclose Confidential Information.

20. **To Whom Highly Confidential Information May Be Disclosed.** A Receiving Party may show and deliver Highly Confidential Information only to the following persons:

a. Counsel for the Receiving Party, including the attorneys, paralegals,

stenographic, and clerical staff employed by such counsel to whom it is reasonably necessary to disclose the information for purposes of the litigation;

b. The Receiving Party's in-house counsel to whom it is reasonably necessary to disclose the information for purposes of the litigation and who have signed the "Acknowledgement and Agreement to Be Bound" (attached here as Exhibit A);

c. Any outside consultant or expert to whom it is reasonably necessary to disclose Highly Confidential Information and who has signed the "Acknowledgement and Agreement to be Bound" (attached hereto as Exhibit A);

d. Any deponent or witness at deposition, trial, or hearing, for whom it appears on the face of the document that the deponent or witness authored or received a copy of the document containing the information, or is or was employed by the Supplying Party;

e. Any special master, mediator, or arbitrator engaged by the parties or authorized by the Court for purposes of mediation, arbitration, or other dispute resolution regarding issues arising in this litigation;

f. Stenographic employees and court reporters recording or transcribing testimony; and

g. The Court and any members of its staff to whom it is necessary to disclose Highly Confidential Information.

21. **Disclosure of Highly Confidential Information to Outside Consultants or Experts.** Before disclosing Highly Confidential Information to any person, the party wishing to make such disclosure shall use diligent efforts to determine whether the person is currently employed by or currently consults with a Competitor regarding any medical device product. If so, the party wishing to make such disclosure shall give at least ten (10) days advance notice in



writing to the counsel for the Supplying Party who designated such information as Highly Confidential, stating the name and address of the person to whom the disclosure will be made and the nature of his or her affiliation with a Competitor. If, within the 10-day period, the Supplying Party objects to the proposed disclosure, then the parties shall meet and confer with respect to the Supplying Party's objection, during which time the party seeking disclosure may not disclose any Highly Confidential Information to that person. If the parties are unable to reach agreement within an additional seven (7) days, the Supplying Party may file a motion for an additional protective order to prevent the disclosure. The party seeking disclosure may not disclose any Highly Confidential Information to the person until thirty (30) days have elapsed after the date of the Court order denying the motion, subject to any subsequent orders of the Court or the applicable appellate court during that time period. If the Court allows disclosure of the Highly Confidential Information, the Information remains Highly Confidential Information and the person shall be bound by this Order. This disclosure obligation shall be a continuing one. If an outside consultant or expert is going to work for, consult with, or otherwise communicate with a Competitor regarding any medical device, counsel for the party consulting with that person shall provide the notice required by this paragraph.

22. **Disclosure to Others Requires Consent or Court Order.** Disclosure of Confidential Information or Highly Confidential Information beyond the terms of this Order may be made only if the Supplying Party designating the material as Confidential Information or Highly Confidential Information consents in writing to such disclosure or the Court orders such disclosure. The terms of this Order shall not apply to any publicly available information or documents.

23. **Confidential Information and Highly Confidential Information Must be**

**Filed Under Seal.** A party may not file in the public record any Confidential Information or Highly Confidential Information without written permission from counsel of record for the Supplying Party or an order secured from the Court.

a. A party that seeks to file any Confidential Information or Highly Confidential Information obtained as a result of such information being produced or disclosed pursuant to this Order must do so under seal in accordance with and subject to the law and rules of the Court.

b. When submitting deposition testimony pursuant to this paragraph that has been designated Confidential or Highly Confidential, the submitting party shall submit, to the extent reasonably possible, only those pages of the deposition transcript that are cited, referred to, or relied on by the submitting party.

24. **Use of Confidential Information and Highly Confidential Information at Trial.** The use of Confidential Information or Highly Confidential Information during trial will be addressed in a later agreement between the parties, or, if they cannot reach agreement, by further order of the Court. Until such a later agreement is reached or order is issued, any party wishing to file documents containing Confidential Information or Highly Confidential Information or otherwise use Confidential Information or Highly Confidential Information in court in any fashion must comply with paragraph 23.

25. **Order Shall Not Restrict Advice to Clients.** Notwithstanding any other provisions hereof, nothing herein shall restrict any party's counsel from rendering advice to its or their clients with respect to this matter, provided that in rendering such advice, counsel shall not disclose any other party's Confidential Information or Highly Confidential Information other than in a manner provided for in this Order.

26. **Unauthorized Disclosure of Confidential or Highly Confidential Information.**

If a Receiving Party learns, by inadvertence or otherwise, of any unauthorized disclosure of Confidential Information or Highly Confidential Information, the Receiving Party must immediately: (1) notify the Supplying Party in writing of the unauthorized disclosure; (2) use its best efforts to receive all unauthorized copies of the information; (3) make all reasonable efforts to prevent further disclosure by each unauthorized person who received such information; (4) inform the person or persons to whom unauthorized disclosures were made about the terms of this Order; and (5) request such person or persons execute the "Acknowledgement and Agreement to Be Bound" attached hereto as Exhibit A.

27. **Use of Party's Own Confidential Information and Highly Confidential Information.** Nothing contained in this Order shall preclude any party from using its own Confidential Information or Highly Confidential Information in any manner it sees fit, without prior consent of any party or the Court.

28. **Confidentiality Extends to Work Product.** All counsel shall at all times keep secure all notes, abstractions, or other work product derived from or containing Confidential Information or Highly Confidential Information. Counsel is obligated to maintain the confidentiality of such work product and shall not disclose or reveal the contents of said notes, abstractions or other work product after the documents, materials, or other things, or portions thereof (and the information contained therein). Nothing in this Order requires the Receiving Party's counsel to disclose work product at the conclusion of the case.

29. **Notice of Receipt of Subpoena Or Court Order Pertaining to Any Discovery Materials.** Any party that is served with a subpoena, court order issued in other litigation, or other notice compelling the production of discovery materials produced by another party must:



- a. Immediately give written notice of such subpoena, court order, or other notice to the original Supplying Party;
- b. Promptly notify in writing the party who caused the subpoena or order to be issued in the other litigation that some or all of the material covered by the subpoena or order is subject to this Protective Order and include a copy of this Order; and
- c. Cooperate with respect to all reasonable procedures sought to be pursued by the Supplying Party.

If the Supplying Party timely seeks a protective order, the party served with the subpoena, court order, or other notice shall not produce any information designated in this action as Confidential Information or Highly Confidential Information before a determination by the Court from which the subpoena or order issued, unless the party has obtained the Supplying Party's permission. The Supplying Party shall bear the burden of seeking protection of its confidential material in that Court.

30. **Survival of Protective Order.** Throughout and after the conclusion of this litigation, including any appeals, the restrictions on communication and disclosure provided in this Order shall continue to be binding upon the parties and all other persons to whom Confidential and Highly Confidential material has been communicated or disclosed pursuant to the provisions of this Order.

31. **Modification of Order.** The terms of this Order may be amended or modified only by written agreement of the parties, or upon motion and order of the Court.

32. **No Impact on Regulatory Reporting.** Notwithstanding any other provision in the order, nothing in this Order shall affect or modify Defendant's ability to review Plaintiffs' information and report such information to any applicable regulatory agencies.

**IT IS SO STIPULATED**, through Counsel of Record.

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*Attorneys for Defendant*

Dated: November 5, 2020

Dated: November 5, 2020

**IT IS ORDERED** that the forgoing Stipulation is approved.

November 5, 2020

Louis L. Stanton  
Judge Louis L. Stanton  
U.S. District Court  
Southern District of New York

**EXHIBIT A**

**ACKNOWLEDGMENT AND AGREEMENT TO BE BOUND**

My name is \_\_\_\_\_

I am employed by \_\_\_\_\_

My full business address is \_\_\_\_\_

My telephone number is \_\_\_\_\_

I have read in its entirety and understand the Protective Order ("Order") entered into between Plaintiffs and Defendant in the case of *Kenneth Dunham and Martha Dunham v. Covidien LP*, 1:19-cv-02851-LLS. I understand I may receive Confidential Information or Highly Confidential Information as described in the Order. By executing this Acknowledgement, I agree to comply with and to be bound by all the terms of the Order. I agree not to disclose Confidential Information or Highly Confidential Information as described in the Order to any person not entitled to receive it and agree not to use such information except in connection with this case.

**FOR INDIVIDUALS RECEIVING HIGHLY CONFIDENTIAL INFORMATION:**

I certify that I am not currently employed by and do not currently consult with any Competitor (as that term is defined in the Order) regarding any medical device, or, if I cannot so certify, I understand that counsel for the party wishing to consult with me must disclose my name, address, and the nature of my affiliation with a Competitor to the Supplying Party prior to disclosing Highly Confidential Information to me. I further understand that if I intend to work for, consult with, or otherwise communicate with any Competitor regarding any hernia mesh medical device, I must immediately notify counsel for the party wishing to consult with me so they may make the necessary disclosure.

I understand and acknowledge that failure to comply with each of the provisions of the Order could expose me to sanctions and punishment in the nature of contempt of court or any other penalties authorized by law or statute. I consent to and accept, generally and unconditionally, the jurisdiction of the U.S. District Court for the Southern District of New York for the enforcement of the Order.

I declare under penalties of perjury that the foregoing is true and correct.

\_\_\_\_\_  
Declarant Signature

Date \_\_\_\_\_